Introduced by Senators DeSaulnier and Steinberg (Coauthors: Senators Hancock, Lieu, Pavley, and Price)

(Coauthor: Assembly Member Blumenfield)

February 22, 2013

An act to add Section 805.8 to the Business and Professions Code, to amend Sections 11165 and 11165.1 of the Health and Safety Code, and to add Part 21 (commencing with Section 42001) to Division 2 of the Revenue and Taxation Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 809, as amended, DeSaulnier. Controlled substances: reporting. (1) Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

Existing law requires dispensing pharmacies and clinics to report, on a weekly basis, specified information for each prescription of Schedule II, Schedule III, or Schedule IV controlled substances, to the department, as specified.

This bill would establish the CURES Fund within the State Treasury to receive funds to be allocated, upon appropriation by the Legislature, to the Department of Justice for the purposes of funding CURES, and would make related findings and declarations.

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This bill would require the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine to increase the licensure, certification, and renewal fees charged to practitioners under their supervision who are authorized to prescribe or dispense controlled substances, by up to 1.16%, the proceeds of which would be deposited into the CURES Fund for support of CURES, as specified. This bill would also require the California State Board of Pharmacy to increase the licensure, certification, and renewal fees charged to wholesalers, nonresident wholesalers, and veterinary food-animal drug retailers under their supervision by up to 1.16%, the proceeds of which would be deposited into the CURES Fund for support of CURES, as specified.

(2) Existing law permits a licensed health care practitioner, as specified, or a pharmacist to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care. Existing law also authorizes the Department of Justice to provide the history of controlled substances dispensed to an individual to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

This bill would require licensed health care practitioners, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care, and, upon the happening of specified events, to access and consult that information prior to prescribing or dispensing Schedule II, Schedule III, or Schedule IV controlled substances.

(3) Existing law imposes various taxes, including taxes on the privilege of engaging in certain activities. The Fee Collection Procedures Law, the violation of which is a crime, provides procedures for the collection of certain fees and surcharges.

This bill would impose a tax upon qualified manufacturers, as defined, for the privilege of doing business in this state, as specified. This bill would also impose a tax upon specified insurers, as defined, for the privilege of doing business in this state, as specified. The tax would be administered by the State Board of Equalization and would be collected by the State Board of Equalization pursuant to the procedures set forth

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in the Fee Collection Procedures Law. The bill would require the board to deposit all taxes, penalties, and interest collected pursuant to these provisions in the CURES Fund, as provided. This bill would also allow specified insurers, as defined, to voluntarily contribute to the CURES Fund, as described. Because this bill would expand application of the Fee Collection Procedures Law, the violation of which is a crime, it would impose a state-mandated local program.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

(5) This bill would declare that it is to take effect immediately as an urgency statute.

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the 2
- following: 3 (a) The Controlled Substance Utilization Review and Evaluation
- 4 System (CURES) is a valuable investigative, preventive, and
- educational tool for law enforcement, regulatory boards,
- educational researchers, and the health care community. Recent
- budget cuts to the Attorney General's Division of Law Enforcement 8 have resulted in insufficient funding to support the CURES
- Prescription Drug Monitoring Program (PDMP). The PDMP is
- 10 necessary to ensure health care professionals have the necessary

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- 11 data to make informed treatment decisions and to allow law 12
 - enforcement to investigate diversion of prescription drugs. Without a dedicated funding source, the CURES PDMP is not sustainable.
 - (b) Each year CURES responds to more than 60,000 requests from practitioners and pharmacists regarding all of the following:
 - (1) Helping identify and deter drug abuse and diversion of prescription drugs through accurate and rapid tracking of Schedule II, Schedule III, and Schedule IV controlled substances.
- 19 (2) Helping practitioners make better prescribing decisions.
- 20 (3) Helping reduce misuse, abuse, and trafficking of those drugs.

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(c) Schedule II, Schedule III, and Schedule IV controlled substances have had deleterious effects on private and public interests, including the misuse, abuse, and trafficking in dangerous prescription medications resulting in injury and death. It is the intent of the Legislature to work with stakeholders to fully fund the operation of CURES which seeks to mitigate those deleterious effects, and which has proven to be a cost-effective tool to help reduce the misuse, abuse, and trafficking of those drugs.

SEC. 2. Section 805.8 is added to the Business and Professions Code, to read:

805.8. (a) (1) The Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine shall increase the licensure, certification, and renewal fees charged to practitioners under their supervision who are authorized pursuant to Section 11150 of the Health and Safety Code to prescribe or dispense Schedule II, Schedule III, or Schedule IV controlled substances by up to 1.16 percent annually, but in no case shall the fee increase exceed the reasonable costs associated with maintaining CURES for the purpose of regulating prescribers and dispensers of controlled substances licensed or certificated by these boards.

- (2) The California State Board of Pharmacy shall increase the licensure, certification, and renewal fees charged to wholesalers and nonresident wholesalers of dangerous drugs, licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9, by up to 1.16 percent annually, but in no case shall the fee increase exceed the reasonable costs associated with maintaining CURES for the purpose of regulating wholesalers and nonresident wholesalers of dangerous drugs licensed or certificated by that board.
- (3) The California State Board of Pharmacy shall increase the licensure, certification, and renewal fees charged to veterinary food-animal drug retailers, licensed pursuant to Article 15 (commencing with Section 4196) of Chapter 9, by up to 1.16 percent annually, but in no case shall the fee increase exceed the reasonable costs associated with maintaining CURES for the

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purpose of regulating veterinary food-animal drug retailers licensed or certificated by that board.

- (b) The funds collected pursuant to subdivision (a) shall be deposited in the CURES accounts, which are hereby created, within the Contingent Fund of the Medical Board of California, the State Dentistry Fund, the Pharmacy Board Contingent Fund, the Veterinary Medical Board Contingent Fund, the Board of Registered Nursing Fund, the Osteopathic Medical Board of California Contingent Fund, the Optometry Fund, and the Board of Podiatric Medicine Fund. Moneys in the CURES accounts of each of those funds shall, upon appropriation by the Legislature, be available to the Department of Justice solely for maintaining CURES for the purposes of regulating prescribers and dispensers of controlled substances. All moneys received by the Department of Justice pursuant to this section shall be deposited in the CURES Fund described in Section 11165 of the Health and Safety Code.
- SEC. 3. Section 11165 of the Health and Safety Code is amended to read:
- 11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES accounts within the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Osteopathic Medical Board of California Contingent Fund, the Veterinary Medical Board Contingent Fund, the Optometry Fund, the Board of Podiatric Medicine Fund, and the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.
- (b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds for the Department of Justice for the purpose of finding CURES. The department may seek and use grant funds to pay the costs incurred from the reporting of

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substance prescriptions to CURES.

controlled substance prescriptions to CURES. The department shall make information about the amount and the source of all private grant funds it receives for support of CURES available to the public. Grant funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled

- (c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency, as described in this subdivision, shall not be
- (d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

disclosed, sold, or transferred to any third party.

- (1) Full name, address, and telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
- (2) The prescriber's category of licensure and license number, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal

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1 controlled substance registration number of a government-exempt 2 facility.

- (3) Pharmacy prescription number, license number, and federal controlled substance registration number.
- (4) National Drug Code (NDC) number of the controlled substance dispensed.
 - (5) Quantity of the controlled substance dispensed.
- (6) International Statistical Classification of Diseases, 9th revision (ICD-9) Code, if available.
 - (7) Number of refills ordered.

- (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
 - (9) Date of origin of the prescription.
 - (10) Date of dispensing of the prescription.
- (e) The CURES Fund is hereby established within the State Treasury. The CURES Fund shall consist of all funds made available to the Department of Justice for the purpose of funding CURES. Money in the CURES Fund shall, upon appropriation by the Legislature, be available for allocation to the Department of Justice for the purpose of funding CURES.
- SEC. 4. Section 11165.1 of the Health and Safety Code is amended to read:
- 11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist shall provide a notarized application developed by the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner or pharmacist, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).
- (A) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:
 - (i) Materially falsifying an application for a subscriber.
- 38 (ii) Failure to maintain effective controls for access to the patient activity report.

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(iii) Suspended or revoked federal Drug Enforcement Administration (DEA) registration.

- (iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.
- (v) Any subscriber accessing information for any other reason than caring for his or her patients.
- (B) Any authorized subscriber shall notify the Department of Justice within 10 days of any changes to the subscriber account.
- (2) To allow sufficient time for licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and a pharmacist to apply and receive access to PDMP, a written request may be made, until July 1, 2012, and the Department of Justice may release to that practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.
- (b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.
- (c) (1) Until the Department of Justice has issued the notification described in paragraph (3), in order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.
- (2) Upon the Department of Justice issuing the notification described in paragraph (3) and approval of the application required pursuant to subdivision (a), licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and pharmacists shall access and consult the electronic history of controlled substances dispensed to an individual under his or her care prior to prescribing or dispensing a Schedule II, Schedule III, or Schedule IV controlled substance.
- (3) The Department of Justice shall notify licensed health care practitioners and pharmacists who have submitted the application required pursuant to subdivision (a) when the department determines that CURES is capable of accommodating the mandate

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1 contained in paragraph (2). The department shall provide a copy 2 of the notification to the Secretary of the State, the Secretary of 3 the Senate, the Chief Clerk of the Assembly, and the Legislative 4 Counsel, and shall post the notification on the department's Internet 5 Web site.

- (d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.
- (e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.
- SEC. 5. Part 21 (commencing with Section 42001) is added to Division 2 of the Revenue and Taxation Code, to read:

PART 21. CONTROLLED SUBSTANCE UTILIZATION REVIEW AND EVALUATION SYSTEM (CURES) TAX LAW

42001. For purposes of this part, the following definitions apply:

- (a) "Controlled substance" means a drug, substance, or immediate precursor listed in any schedule in Section 11055, 11056, or 11057 of the Health and Safety Code.
- (b) "Insurer" means—a health insurer licensed pursuant to Part 2 (commencing with Section 10110) of Division 2 of the Insurance Code, a health care service plan licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code), and a workers' compensation insurer licensed pursuant to Part 3 (commencing with Section 11550) of Division 2 an admitted insurer writing health insurance, as defined in Section 106 of the Insurance Code, and an admitted insurer writing workers' compensation insurance, as defined in Section 109 of

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- (c) "Qualified manufacturer" means a manufacturer of a controlled substance doing business in this state, as defined in Section 23101, but does not mean a wholesaler or nonresident wholesaler of dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.
 - 42003. (a) For the privilege of doing business in this state, an annual tax is hereby imposed on all qualified manufacturers in an amount-of _____ dollars (\$____) determined pursuant to Section 42005, for the purpose of establishing and maintaining enforcement of the Controlled Substance Utilization Review and Evaluation System (CURES), established pursuant to Section 11165 of the Health and Safety Code.
 - (b) For the privilege of doing business in this state, a tax is hereby imposed on a one time basis on all insurers in an amount of _____ dollars (\$_____), for the purpose of upgrading CURES.
 - (b) The Department of Justice may seek grant moneys from insurers for the purpose of upgrading and modernizing the CURES. Insurers may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (e) of Section 11165 of the Health and Safety Code. The department shall make information about the amount and the source of all private grant funds it receives for support of CURES available to the public.
 - 42005. Each qualified manufacturer and insurer shall prepare and file with the board a return, in the form prescribed by the board, containing information as the board deems necessary or appropriate for the proper administration of this part. The return shall be filed on or before the last day of the calendar month following the calendar quarter to which it relates, together with a remittance payable to the board for the amount of tax due for that period.

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42007. The board shall administer and collect the tax imposed by this part pursuant to the Fee Collection Procedures Law (Part 30 (commencing with Section 55001)). For purposes of this part, the references in the Fee Collection Procedures Law (Part 30 (commencing with Section 55001)) to "fee" shall include the tax imposed by this part and references to "feepayer" shall include a person required to pay the tax imposed by this part.

42005. (a) The board shall collect the annual tax imposed by this part pursuant to the Fee Collection Procedures Law (Part 30 (commencing with Section 55001)). For purposes of this part, a reference in the Fee Collection Procedures Law to a "fee" shall include this tax and a reference to a "feepayer" shall include a person liable for the payment for the taxes collected pursuant to that law.

- (b) (1) The board shall not accept or consider a petition for redetermination that is based on the assertion that a determination by the Department of Justice incorrectly determined that a qualified manufacturer is subject to the tax or that a determination by the Department of Justice improperly or erroneously calculated the amount of that tax. The board shall forward to the Department of Justice any appeal of a determination that asserts that a determination by the Department of Justice incorrectly determined that a qualified manufacturer is subject to the tax or that a determination by the Department of Justice improperly or erroneously calculated the amount of that tax.
- (2) The board shall not accept or consider a claim for refund that is based on the assertion that a determination by the Department of Justice improperly or erroneously calculated the amount of a tax, or incorrectly determined that the qualified manufacturer is subject to the tax. The board shall forward to the Department of Justice any claim for refund that asserts that a determination by the Department of Justice incorrectly determined that a qualified manufacturer is subject to the tax or that a determination by the Department of Justice improperly or erroneously calculated the amount of that tax.
- 42007. (a) The Department of Justice shall determine the annual tax by dividing the cost to establish and maintain enforcement of CURES by the number of qualified manufacturers. For calendar year 2014, the CURES cost shall be four million two hundred thousand dollars (\$4,200,000). Beginning with the 2015

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1 calendar year, and for each calendar year thereafter, the 2 Department of Justice shall adjust the rate annually to reflect 3 increases or decreases in the cost of living during the prior fiscal 4 year, as measured by the California Consumer Price Index for all 5 items.

- (b) The Department of Justice shall provide to the board the name and address of each qualified manufacturer that is liable for the annual tax, the amount of tax, and the due date.
- (c) All annual taxes referred to the board for collection pursuant to Section 42005 shall be paid to the board.
- 42009. All taxes, interest, penalties, and other amounts collected pursuant to this part, less refunds and costs of administration, shall be deposited into the CURES Fund.
- 42011. The board shall prescribe, adopt, and enforce rules and regulations relating to the administration and enforcement of this part.
- SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.
- SEC. 7. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:
- In order to protect the public from the continuing threat of prescription drug abuse at the earliest possible time, it is necessary this act take effect immediately.